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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/772,185 | 02/04/2004 | Jude S. Sauer | LS-006CV | 4686 |

7590 11/29/2010
Kenneth J. LuKacher, Esq.
South Winton Court
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| EXAMINER |
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NGUYEN, VI X

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| ART UNIT | PAPER NUMBER |
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3731

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| MAIL DATE | DELIVERY MODE |
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11/29/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/772,185 | Applicant(s) SAUER, JUDE S. | |
| | Examiner VICTOR X. NGUYEN | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15-18 and 20-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 9 and 20-24 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-7, 10, 15-18, 25-28, 30-31 is/are rejected.
- 7) ☒ Claim(s) 4, 5 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Action is in response to applicant's pre-brief conference filed on 6/1/2010. Upon further consideration, new grounds of rejection are made below.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-3, 6-7, 10, 15-18, 25-28, 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiber US 4,883,458.

Claim 1: Shiber discloses a proximal end having a housing 27; a shaft 71 extending from said housing to a distal end of the instrument, said shaft having at said distal end an opening (figure 2, the opening occurs where a guidewire 14 goes through) to outside of said instrument; a guide tube 21 extending from said shaft through said opening of said shaft in which said guide tube 21 comprises an outer tubular surface, two ends, and an opening extending through said guide tube between said ends of said guide tube; a path, fig. 2 through at least said opening of said guide tube for extending a guide wire (14); and means for longitudinally cutting tissue (see col. 3, lines 33-67) guided along the outer tubular surface of said guide tube through said opening of said shaft, said means comprising a blade (22/23) extendable and retractable through said opening of said shaft to cut tissue when present outside of said instrument.

Claims 2-3: Shiber discloses the longitudinally cutting means (fig. 2) provides a cut of a predetermined depth and width; and wherein said longitudinally cutting means further comprises

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means at said housing coupled to said blade for remotely controlling the extending and retracting of said blade at said distal end (see col. 3, lines 33-67).

Claims 6-7: Shiber discloses when a guide wire 14 is extended along said path said distal end is located adjacent tissue along said guide wire to be cut when said blade is extended; and wherein said shaft is extendable through an endoscope (see col. 1, lines 59-63). It is noted that the limitation "said shaft is extendable through an endoscope" (an intended use limitation): a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use then it meets the claim (see MPEP 2106).

Claims 10, 15, 16: Shiber discloses the shaft is rigid or flexible; wherein said shaft is positionable in a tubular tissue structure through which said distal end of the instrument is guided by the guide wire along the path for extending said guide wire 14 (fig. 2) and said blade when extended provides the longitudinally incision along a narrowed region of the tubular structure; and wherein the guide tube 21 is non-movable with respect to the shaft.

Claims 17-18: Shiber discloses the path for extending the guide wire 14 extends through said housing, said shaft 71, and said guide tube 21, and then exits said guide tube; wherein said blade 22/23 is external of said guide tube and has a single longitudinally oriented sharp edge, and said means disposes said blade to extend longitudinally along the outer tubular surface of said guide tube through said opening of said shaft to enable said edge of said blade to make a longitudinal incision in tissue when present outside of said instrument (fig. 2).

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Claim 25: Shiber discloses as best seen in figures 11-14, a shaft 42 having an end; a blade 41 at said distal end movable to extend out of said shaft to cut tissue when present outside of said instrument; and a member 50 which guides movement of said blade at said distal end out of said shaft; wherein said member 50 is non-movable with respect to said shaft, and said blade 41 is movable with respect to said member.

Claims 26-28: Shiber discloses wherein said the member 50 has an outer surface and said blade 41 is guided along said outer surface of member outside said shaft; wherein said shaft 42 has an opening to outside of said instrument (fig.13), and said blade extends out of said shaft through said opening to cut tissue outside of said instrument which neighbors said guide member; and wherein said outer surface of said member 50 represents a tubular outer surface 42.

Claims 30-31: Shiber discloses the member has a passage for extending a guidewire 14 through the member (fig.13); and wherein a shaft 42 having an end; a blade 41 at said end movable to extend out of said shaft to cut tissue when present outside of said instrument; and a guide member 50 which guides movement of said blade 41 at said end out of said shaft, wherein said blade is located external of said guide member, and said blade is movable with respect to said guide member 50 as best seen in fig. 13, col. 5, lines 40-54.

Allowable Subject Matter

3. Claims 8-9, 20-24 allowed over the art of record.
4. Claims 4-5, 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Response to Arguments

5. Applicant's arguments filed on 6/1/2010 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTOR X. NGUYEN whose telephone number is (571)272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victor X Nguyen/
Examiner, Art Unit 3731